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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,776	11/30/2001	Dana V. Ferraris	2824-226	4606

7590 12/24/2003

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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/996,776	Applicant(s) FERRARIS ET AL.	
	Examiner Bruck Kifle, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 15 and 18 is/are allowed.
- 6) ☐ Claim(s) 13,14,16,17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/27/03</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1624

Applicant's amendments and remarks filed 10/27/03 have been received and reviewed. Claims 1-24 are still pending in this application.

This application contains claims 1-12 drawn to nonelected subject matter. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Also, dependencies of claims 13-24 should be appropriately corrected.

Claims 13-24 are under consideration.

Claim Rejections - 35 USC § 112

Claims 13, 14, 16, 17 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) The phrase "when present" is still present in claims 16 and 17.
- ii) The group "halogen-substituted amino" is unclear. Applicants state that this "is an amino group substituted with a halogen moiety." Is a group such as -NCl₂, -N(Cl)(Br), etc. intended? It is unclear how this is possible. Further clarification is requested.
- iii) Regarding the term "substituted," Applicants say that one skilled in the art would understand what is claimed when the claim is read in light of the specification. However, the specification does not say what the substituents are included. The substituents are limited to examples. Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

iv, v, vi) The terms "cycloalkyl," "heteroaryl" and "heterocyclo" are still indefinite. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. The U.S. Court of claims held to this standard in *Lockhead Aircraft vs. Unites States*, 193 USPQ 449, "claims measure the invention and resolution of invention must be based on what is claimed." The CCPA said, "that invention is the subject matter defined by the claims submitted by the applicant." "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim" (*In re Priest*, 199 USPQ 11 at 15).

Therefore Applicants need to indicate in the claim what is intended.

vi) Applicants have merely stated that the term "heterocycloalkyl" is well understood nomenclature. Is it a "heterocycle" or is it a "heterocycle-alkyl"? A clarification is required.

vii) Regarding claim 19, where it was deemed unclear what is achieved by inhibiting PARP activity in a mammal, why a given mammal needs inhibiting of PARP activity and whether a given animal needs or does not need inhibiting PARP activity, Applicants say that the specification describes these in pages 1-6. This claim would read on PARP inhibition in mammals with below normal PARP activity, PARP inhibition in mammals with normal PARP activity, or in asymptomatic mammals with up-regulated PARP activity. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' inhibitor falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967). As the

Art Unit: 1624

Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

viii) In claim 13, R₄ is defined three times. The purpose of the last definition is unclear.

Claims 19, 20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method of use claims are drawn to inhibiting PARP activity and thereby treating any and all of the diseases recited. Treating all of these diseases using a single drug is not prima facie enabled for the reasons given in the previous office action. Applicant's arguments have been fully considered but not found persuasive. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference.

Art Unit: 1624

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A proviso has been included in claim 13 that reads "wherein at least one of R₁, R₂, R₃ and R₄ is independently halogen, amino, hydroxy,". This proviso lacks description. Even negative limitations require a description. The MPEP at 2173.05(i) Negative Limitations states "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984)" and, further, "Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement." In the instant case, the new concept that has been introduced by the proviso is the specific relationships between the variables R₁, R₂, R₃ and R₄. This specific relationship of connectivity was previously not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

Applicant is advised that should claim 19 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Art Unit: 1624

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.


Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al. (Chemical & Pharmaceutical Bulletin (1974), 22(6), 4131-2). These claims read on the compound Benzo[c]-1, 6-naphtyridin-6(5H)-one (see CAS abstract and structure).

Claims 15 and 18 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 703-305-4484. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
December 19, 2003